REMARKS/ARGUMENTS

Amendment to the Claims

Claims 1-5, 7-40, 45, 47-54 are currently in the application. Claims 12, 18, 23-27, 31-35, 37-40, 45, and 47-48 are withdrawn from consideration. Claims 7 and 28 are amended.

Claim 7 is presently amended, to correct grammar.

Claim 28 is amended to provide that the injection end extends to a distance sufficient for intramuscular insertion.

Rejections under 35 USC §103(a)

Claim 1-5, 7-11, 13-17, 19-22, 28-29, 30, 36, and 49-54 are rejected as obvious over Newman (us 5,616,132) and further in view of Flaherty (US 7,303,549) and further in view of Ueda et al. (US 7,252,653 and Rise (US 5,752,930).

The Examiner also makes the rejection a final rejection.

Applicant traverses.

A. The Final Rejection is Premature and should be withdrawn.

Claim 1 had not been amended and is the original claim. In the last non-final response on December 4, 2006, claim 1 was rejected as obvious over Pike in view of Miskinyar. Applicant traversed the rejection in the response filed on March 8, 2007.

The present rejection of claim 1 is rejected based on entirely new prior art. Three of the references cited in the rejection were not disclosed in an IDS by the Applicant, and the fourth cited reference was disclosed in an IDS by the Applicant well before the first action.

The rejection expressly states that the rejection is on "new grounds". According to MPEP 706.07(a), when the examiner introduces a new ground of rejection that is neither (1) necessitated by applicant's amendment to the claims, nor (2) based on information submitted in an IDS during the period set forth in 37 CFR 1.97(c), which is inapplicable in this case, a final rejection is never proper.

Similarly, claims 2-4, 9-11, 13, 14-17, 19-22, 28-30, and 36 were either original or were amended in a minor, non-substantive manner, and all of claims 2-4, 9-11, 13, 14-17, 19-22, 28-

30, and 36 were rejected on new grounds that were not necessitated by an applicant amendment, nor based on information submitted in an IDS during the period set forth in 37 CFR 1.97(c).

Therefore, the final rejection should be withdrawn.

B. The rejection fails to state a prima facie obviousness rejection

Independent claims 1 and 5, provide, *inter alia*, that the device provide painless, inter-muscular injection of a liquid medicament, having a needle that extends from the base to a distance sufficient for intermuscular insertion of the injection end of the needle.

Independent claims 9, 14, and 19 provide, *inter alia*, that the means for pumping provide a substantially constant volumetric flow rate of from about 0.5 μL/s to about 20 μL/s.

The Newman reference (US 5,616,132) describes insertion of the needle into the skin, but does not disclose a device that extends the needle to a distance from the base sufficient for intermuscular injection, nor any flow rate of the liquid from the reservoir.

The Flaherty reference (US 7,303,549) describes a device for inserting a canula into the skin for injection of a liquid into the skin, and likewise does not disclose that the canula tip extends to a distance sufficient for intermuscular injection, nor any flow rate of the liquid from the reservoir.

The Ueda et al reference (US 7,252,653, filed (PCT) Jan 23, 2002), discloses a tapered injection needle affixed to the end of a hand-held syringe for injecting the liquid. The rejection states that Ueda et al discloses the "benefit of having needles with the specific claimed dimensions (see entire reference)". The rejection however fails to provide any explanation that a person of ordinary skill in the art would have recognized that applying the technique of Ueda et al. would have yielded predictable results in the device of Newman. Newman requires that the hypodermic needle have both ends shaped to pierce their respective sheaths (col 3 lines 3-6). Ueda et al teaches a needle that tapers from the injection end to an anchoring part 22 , which purposely sized larger that the insertion part 21 of the needle in order to reduce liquid flow resistance (col 7 lines 5-8) and to improve attachment of the needle to the supporting part 3 of the syringe (col 7 lines 27-30).

Further, there is no teaching, suggestion or motivation in either Newman or Flaherty to modify their needle portions as suggested by Ueda et al. Neither reference mentions or suggest that needle-stick pain is a problem or need. Applicant also does not considered that a person of

ordinary skill would look to the hand-held syringe art for an improvement in a skin-attached injection device, particular for a benefit which is not indicated as a problem or a need.

Finally, the Rise reference (US 5,752,910) teaches using a syringe with a hypodermic needle 16 to rapidly fill an under-the-skin injection device through a septum 18 in a port 14 disposed in the injection device, as seen in Fig. 1 and described at col 2 line 66 to col 3 line 6. The alleged flow rate in Rise of 1 μL/min to 5000 μL/min is occurring only is short bursts covering a first time period ranging from 0.01 seconds to 2.0 seconds, while the flow rate is shut off or zero during a succeeding second time period that runs from 8 seconds to 672 hours. Rise discloses (claim 7) an average flow rate is from 0.01 μL/hr (2.8×10^{-6} μL/sec) to 20 μL/min (0.33 μL/sec), which is outside the claimed flow rates.

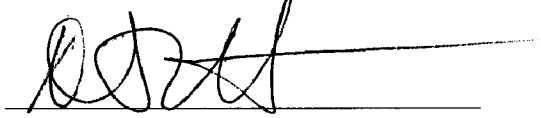
Therefore, Applicant believes that the rejection fails to state a *prima facie* obviousness rejection against any of the claims.

Conclusion

Applicant believes a complete response to the office action has been provided, and that the present invention as claimed clearly distinguishes the teachings of the prior art of record. Applicant requests a prompt allowance of all claims. In any event, the finality of the previous rejection must be withdrawn.

Respectfully submitted,

For: Eric James WALL

By: 

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